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10/674,371	09/30/2003	Don A. Tanaka	END5098-0515140	5198

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EXAMINER
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RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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10/11/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dbell@fbtlaw.com  
rgaunce@fbtlaw.com

## Office Action Summary

Application No.

10/674,371

Applicant(s)

TANAKA ET AL.

Examiner

Melissa Ryckman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on received on 5/18/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10, 15, 17, 19 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 15, 17, 19 and 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to claims filed 5/18/07A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/20/07 has been entered.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the petal tip flaring directionally inward towards the longitudinal axis" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant has not disclosed "the petal tip flaring directionally inward towards the longitudinal axis when the anastomotic device is in the unactuated position".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The applicant states "the petal tip flaring directionally outward away from the tissue wall" is interpreted by the examiner and verified by the applicant's attorney Andrew Ulmer (called 9/28/07) to be "the petal tip flaring directionally outward away from" the longitudinal axis.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 15, 17, 19 and 23-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (US Patent No. 6,673,084).

Peterson teaches an anastomotic device (Fig. 20a), comprising a slidably woven tube of at least one wire strand, the woven tube defining a longitudinal axis, and the woven tube having each longitudinal end terminate in slidably engaging circumferential petals (portion 88f and 86f can slide against each other), the woven tube having an unactuated position (Fig. 26) of a generally cylindrical shape and an actuated position (Fig. 29) of a hollow rivet shape respectively for insertion through and for forming an anastomotic attachment defining a hollow opening between two proximate tissue walls at an anastomotic surgical site (Fig. 29), wherein each petal (88f) comprises a petal tip flaring directionally inward (Fig. 26, proximal portion of 88f is flaring inward) towards the longitudinal axis when the anastomotic device is in the unactuated position, and the

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petal tip flaring directionally outward (Fig. 29) away from (proximal portion of 88f is flaring outward, Fig. 29) the longitudinal axis when the anastomotic device is in the actuated position, and as said anastomotic device moves from the unactuated to the actuated position, the direction of the flare reduces sliding friction between moving petals (Figs. 26-29), and when the anastomotic device is in the actuated position, the direction of the flare reduces pressure on tissue captured between the tip of each petal (Fig. 29).

Claim 15:

Peterson teaches the woven tube comprises at least one strand (85f) having unattached ends (Fig. 20a).

Claim 17:

Peterson teaches the unattached ends (85F) each terminate in a loop (Fig. 29).

Claim 19:

Peterson teaches an underlying portion of each circumferential petal is shaped to diverge from an overlying portion of an adjacent petal for mitigating resistance to actuation (Fig. 29).

Claim 23:

Peterson teaches the flaring of each circumferential petal tip (88f) comprises a monotonic slope toward a distal tip of the petal (Fig. 29).

Claim 24:

Peterson teaches at least a portion of each petal has an uncurved section (proximal portion of 88f in Fig. 27 is uncurved).

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Claim 25:

Peterson teaches the unattached end of each loop (85f) is positioned adjacent to another portion of the loop to shield the unattached end from tissue contact (the distal portion of 85f is away from the tissue, Fig. 29).

Claim 26:

Peterson teaches the anastomotic device is in the deployed position, the loops are orientated to position the unattached ends away from tissue contact (the distal portion of 85f is away from the tissue, Fig. 29).

Claim 27:

Peterson teaches the unattached ends (85f) are flared in the same direction (Fig. 27) as the petal tips (88f).

Claim 28:

Peterson teaches the unattached ends (85f) extend outside of the woven petals Fig. 29 and 20a).

Claim 29:

Peterson teaches the anastomotic device is configured to operably engage with an anastomotic device applier (254) and the unattached ends (85f) are configured to avoid interference with the applier when moving the anastomotic device from the unactuated to the actuated position (Figs. 26-29).

Claim 30:

Peterson teaches the wire has shape memory effect properties (col. 2, ll. 8).

***Response to Arguments***

Applicant's arguments with respect to claims 10, 15, 17, 19 and 23-30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

  
(JACKIE) TAN-UYEN HO  
SUPERVISORY PATENT EXAMINER